

## **REMARKS/ARGUMENT**

### **Description of Amendments**

Claims 28, 44, 50, 52, 54 and 58-61 are pending. Claim 62 is new and Claim 45 canceled. Claim 44 contains the same scope as Claim 45. Thus, Claim 45 was not narrowed in response to the Official Action.

### **Duty of Disclosure**

Applicants would like to bring to the Examiner's attention the following patent applications: 11/840,147; 12/184,347; 10/880,025; 10/235,033 (now U.S. Patent No. 6,723,120); 08/837,993 (now U.S. Patent No. 6,240,616); and 11/173,713. The current application is a divisional of the '033 application. Applicants assume that the Examiner, for consistency in examination by the Office, will coordinate the examination of the current application with these other applications.

### **Rejection under 35 U.S.C. § 103**

Independent Claims 28 and 44 stand rejected under 35 USC § 103(a) as unpatentable over *Khosravi* (US5441515) taken in combination with two MacGregor patents, *MacGregor '426* (US4355426) and *MacGregor '253* (US5015253).

As best understood, the Office concludes at paragraph 5, that *MacGregor '253* disclosed, among other things, "an outer disposed on the outer side and an inner layer disposed on the inner side, where the outer layer is made from a first porous material formed by particles sintered to the . . . [outer] core; where the inner layer is made from a second porous material formed by particles sintered to the . . . [outer] core;" but that the layers were not of "metallic material". As to *MacGregor '426* the Office felt that its disclosure of a metallic core and layer of sintered material for implants or devices (excluding expanding stents or grafts), when read in combination with *MacGregor '253* would have led one of ordinary skill in the art to apply "a metallic material in the layers of the stent of *MacGregor '253*. A metallic material would allow a stent to have biocompatible, porous layers with excellent wear and strength characteristics."

**The Office misreads *MacGregor* '253.** This reference discloses a method of forming a stent by winding strands of material about a mandrel. It specifically notes that the method of forming the structure is that method described in US4475972. *See* col. 2, ll. 57-61 and col. 4, ll. 21-35 of *MacGregor* '253. An inspection of US4475972, or simply *MacGregor* '253 will reveal that a so-called porous network for the structure 21 is formed by overlapping wires that form a porous network:

The angle at which the strand material is drawn and wound onto the mandrel may be defined as an acute angle with respect to the axis of the graft or mandrel on which the strand material is wound. By varying the angle at which the strand material is wound onto the mandrel, the size and shape of the pores 33 formed by and within the network of overlapping layers of wire, and therefore the overall porosity of the stent 21, may be selected. Specifically, a smaller angle of winding 65 generally will result in smaller-sized pores 33 and reduced total porosity of the stent.

Col. 4, ll. 59-66. Further, in one particular embodiment, the “[a] sintered beaded structure . . . applied to the surface of the stent 21” supposedly enhances the biocompatibility and hemocompatibility of the stent 21. col. 5, ll. 51-60. Thus, according to this embodiment the pores of the network of overlapping wires becomes more intricate because there is sintered beads of material deposited on the overlapping wires.

***MacGregor* '253 as modified by *MacGregor* '426 does not disclose separate porous layers as claimed.** This disclosure, however, does not disclose the elements of Claim 28 as alleged in the Official Action (see paragraph 5). In particular, *MacGregor* '253 does not teach or suggest

wherein the strut element includes a solid metallic inner core having an inner side and an opposed, outer side, an outer layer disposed on the outer side, the outer layer being a **first porous layer of metallic material** formed by particles, filaments or fibers sintered to the inner core, and an inner layer disposed on the inner side, the inner layer being a **second porous layer of metallic material** formed by particles, filaments or fibers sintered to the inner core

At best, *MacGregor* '253 discloses sintered beads of material deposited over a metal wire. This is hardly a disclosure of a strut that has both a “first porous material formed by

particles sintered” and a separate and distinct “second porous material formed by particles sintered”.

***MacGregor ‘253 as modified by MacGregor ‘426 does not disclose separate porous layers arranged to flow radially inward and outward, respectively.*** Claim 28 also recites

wherein the strut is formed from a metallic sheet such that the solid core causes fluid impregnated in the second porous layer to flow **only in a radially inward** direction after the stent has been implanted in a vessel, and

A similar recitation is made in Claim 44. Neither of the MacGregor patents teach or suggest having pores separated from a solid core, so as to cause a fluid to flow only radially inward (second porous layer), in addition to a separate set of pores arranged for flow only in a radially outward (first porous layer) direction. At best, the art only teaches one of these layers. This conclusion necessarily follows from the fact that the structure is forming pores from a nested pattern of wires. There is no solid core in the *MacGregor ‘253* which would make possible the claimed arrangement that causes fluid flow only radially inward and outward directions, respectively.

***No prima facie is made because the requisite fact-finding was fundamentally flawed, as evidenced by paragraph 5 of the Office action and lack of the alleged disclosure in MacGregor ‘253 and MacGregor ‘426.*** It is axiomatic that a *prima facie* case of obviousness is not made if the factual findings under *Graham* were erroneous. As demonstrated above, Applicants have shown that *MacGregor ‘253 as modified by MacGregor ‘426* neither teach the claimed combination of “a first porous layer of metallic material” and “a second porous layer of metallic material”, nor an arrangement whereby there is flow from pores only radially inward or outward, respectively, as alleged in paragraph 5 of the Official Action.

Accordingly, as the Office’s *Graham* findings were erroneous, Applicants respectfully ask that the rejection of Claim 28 be withdrawn and this claim allowed. For similar reasons, Applicants request that the rejection of Claim 45 and all pending dependant claims be withdrawn as well.

For the foregoing reasons Applicants respectfully ask that all non-withdrawn claims be indicated as allowable.

**CONCLUSION**

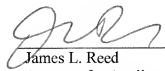
In light of the foregoing remarks, this application is considered to be in condition for allowance, and early passage of this case to issue is respectfully requested. If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 07-1850.

Respectfully submitted,

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